UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
MCALLEN DIVISION

RICARDO A. RODRIGUEZ,	§	
	§	
Plaintiff,	§	
VS.	§	CIVIL ACTION NO. 7:12-CV-330
	§	
AMERICAN MEDICAL SYSTEMS, INC.,	§	
	§	
Defendant.	§	

ORDER GRANTING IN PART DEFENDANT'S RULE 12(B)(6) MOTION TO DISMISS AND GRANTING IN PART DEFENDANT'S PARTIALLY CONVERTED MOTION FOR SUMMARY JUDGMENT

I. Factual and Procedural Background

Now before the Court is Defendant American Medical Systems, Inc.'s ("AMS") Motion to Dismiss under Federal Rule of Civil Procedure 12(b)(6), partially converted by the Court to a Motion for Summary Judgment under Rule 56 on the issue of whether Plaintiff's claims are preempted. (Dkt. Nos. 9, 35).

In his Original Petition, *pro se* Plaintiff Ricardo A. Rodriguez complains of complications following a surgical procedure performed on February 11, 2012 by Dr. Henry E. Ruiz during which Plaintiff was implanted with a "penile inflatable prosthesis AMS 700 MS." (Dkt. No. 1-2, Exh. A).[1] Plaintiff asserts three causes of action against AMS under Texas law: (1) strict liability on the alleged basis that the device was defectively designed and manufactured "in that it causes pain, discomfort, disfigurement, and fails to produce an erection as promised," *id.* at ¶¶ 9-11; (2) generalized violations of the Texas Deceptive Trade Practices Act ("DTPA"), *id.* at ¶¶ 15-16; and (3) breach of contract on the basis of AMS' "actions and/or omissions," *id.* at

[1] As set forth in the Court's prior order, Dr. Ruiz also was joined as a defendant to the action and was dismissed prior to the removal of this case. *See* (Dkt. No. 35). Plaintiff's Original Petition remains the live pleading.

¶ 17. AMS' Motion advances two bases for dismissal: (1) that Plaintiff's claims against it are preempted by the express preemption provision of the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), *see* 21 U.S.C. § 360k(a); and, in the alternative, (2) that Plaintiff's "conclusory" complaint fails to satisfy the federal pleading standard. (Dkt. No. 9). The Court must consider evidence outside the pleadings in addressing the initial basis for dismissal, and therefore will apply the Rule 56 standard in determining whether Plaintiff's claims as pleaded are subject to MDA preemption. *See* (Dkt. No. 35).

Upon review of AMS' Motion and the parties' responsive briefing and evidence provided both prior and subsequent to the Court's partial conversion of the Motion, the Court finds that Plaintiff's breach of contract cause of action cannot survive AMS' Rule 12(b)(6) challenge, and that Plaintiff's remaining claims are preempted therefore partial summary judgment must be granted for the following reasons.

II. Standards of Review

A. Rule 12(b)(6)

A party may move to dismiss under Federal Rule of Civil Procedure 12(b)(6) for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). Rule 12(b)(6) is read in conjunction with the pleading standard set forth in Rule 8(a), which requires "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2); *see Ashcroft v. Iqbal*, 556 U.S. 662, 677-68 (2009). This standard does not require detailed factual allegations. *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). However, a party's "obligation to provide the 'grounds' of his 'entitle[ment]' to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal citations omitted). To survive

a Rule 12(b)(6) motion, the complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). A claim has facial plausibility when the pleaded factual content allows the court, drawing upon its "judicial experience and common sense," to reasonably infer that the defendant is liable for the misconduct alleged. *Id.* at 678 (citing *Twombly*, 550 U.S. at 556), 679. "But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—'that the pleader is entitled to relief.'" *Id.* at 679 (quoting FED. R. CIV. P. 8(a)(2)).

B. Rule 56

A district court must grant summary judgment when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). A fact is material if it might affect the outcome of the lawsuit under the governing law, and is genuinely in dispute only if a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A party moving for summary judgment has the initial responsibility of informing the court of the basis for its motion and identifying those portions of the pleadings and materials in the record, if any, which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986); FED. R. CIV. P. 56(a), (c). Once the moving party carries its burden, the burden shifts to the nonmovant to go beyond the pleadings and provide specific facts showing the existence of a genuine issue for trial. *Celotex*, 477 U.S. at 324; FED. R. CIV. P. 56(c). In conducting its review of the summary judgment record, the court "may not make credibility determinations or weigh the evidence" and must resolve doubts and reasonable inferences regarding the facts in favor of the nonmoving party. *Reeves v. Sanderson Plumbing Prods., Inc.*,

530 U.S. 133, 150 (2000); *Anderson*, 477 U.S. at 255; *Dean v. City of Shreveport*, 438 F.3d 448, 454 (5th Cir. 2006). However, the nonmovant cannot satisfy its burden with "conclusory allegations, speculation, and unsubstantiated assertions which are either entirely unsupported, or supported by a mere scintilla of evidence." *Chaney v. Dreyfus Serv. Corp.*, 595 F.3d 219, 229 (5th Cir. 2010); *see also Brown v. City of Houston*, 337 F.3d 539, 541 (5th Cir. 2003) ("Unsubstantiated assertions, improbable inferences, and unsupported speculation are not sufficient to defeat a motion for summary judgment.").

III. AMS' Motion

A. Summary of Parties' Arguments

AMS contends and presents evidence purporting to show that the device implanted into Plaintiff received approval from the Food and Drug Administration ("FDA") when it completed the agency's product development protocol ("PDP") process, and that PDP completion triggers the express preemption clause of the MDA and forecloses any state-law claim asserted by Plaintiff on the facts alleged. (Dkt. Nos. 9, 16, 37). Plaintiff responds that the evidence does not establish that the device implanted into him has received FDA approval, and in the alternative that he has pleaded a "parallel" claim not subject to MDA preemption. (Dkt. Nos. 15, 36, 38).

In the alternative, AMS submits that Plaintiff's pleaded causes of action fall "far short" of the Rule 12(b)(6) standard. (Dkt. No. 9). Plaintiff offers a generalized counterargument that his claims, when considered against his factual allegations, meet this standard. (Dkt. No. 15).

B. Overview of MDA Preemption

"In response to the concern that state-law governance of medical devices was inadequate, Congress passed the MDA, giving the FDA authority to regulate medical devices and expressly preempting certain state regulations." *Bass v. Stryker Corp.*, 669 F.3d 501, 514-15 (5th Cir.

2012) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315-16 (2008); 21 U.S.C. § 360k). The MDA classifies medical devices into three categories depending on the risks they present, with "Class III" devices receiving the highest level of oversight. *Riegel*, 552 U.S. at 316. Before a Class III device may be introduced to the market, it must receive approval or clearance from the FDA. *See id.* at 317. Most Class III devices are cleared for sale upon determination by the FDA that the device is "substantially equivalent" to a device already on the market at the time the MDA took effect. *Id.* The remaining devices receive FDA approval through the "rigorous" premarket approval ("PMA") process, or are considered as having PMA approval by virtue of their completion of the PDP process. *Id.*; *Betterton v. Evans*, 351 F.Supp.2d 529, 534-35 (N.D.Miss. 2004).[2] The FDA grants PMA approval only when provided with "reasonable assurance" of the device's "safety and effectiveness." *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)). The agency must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," 21 U.S.C. § 360c(a)(2)(C), and "may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives," *Riegel*, 552 U.S. at 318. Once the device has received PMA approval, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)). If the manufacturer wishes to make such a change, it must request and receive supplemental approval from the FDA. *Id.* (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)).

[2] As noted by AMS and the court in *Betterton*, the MDA provides that "[i]n the case of a class III device which is required to have [PMA approval], such device shall be considered as having such an approval if a notice of completion of testing conducted in accordance with a product development protocol approved under paragraph (4) has been declared completed under paragraph (6)." 21 U.S.C. § 360e(f)(1). Further, the governing regulations state that "[a] class III device for which a product development protocol has been declared completed by the FDA under this chapter will be considered to have an approved PMA." 21 C.F.R. § 814.19.

Subject to an exception not relevant here, the MDA includes an express preemption provision which states:

> "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> > (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). As determined by the U.S. Supreme Court in *Riegel* and most recently articulated by the Fifth Circuit in *Bass*, this provision preempts state-law tort claims to recover for injuries allegedly caused by a medical device if: (1) the federal government has established requirements applicable to the device; and (2) the claims relate to safety or effectiveness and are based on state requirements that are different from or in addition to the federal ones. *Bass*, 669 F.3d at 507 (quoting *Riegel*, 552 U.S. at 321-22). PMA approval of a device automatically satisfies the first prong because such approval imposes device-specific, federal requirements: the device "must be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel*, 552 U.S. at 323; *see also id.* As the equivalent of PMA approval, PDP completion also satisfies the "federal requirements" prong. *Malbroux v. Jancuska*, 2011 WL 3816104, at *2 (W.D.La. Aug. 29, 2011) (addressing PDP completion of "AMS 700 Series Inflatable Penile Prosthesis").

"State requirements" include state common-law duties under the meaning of the second prong, such that these duties are preempted if they would require the medical device "to be safer, but hence less effective, than the model the FDA has approved….'" *Riegel*, 552 U.S. at 324-25, 330; *Bass*, 669 F.3d at 508-09; *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 768 (5th Cir.

2011). Thus, a device manufacturer is insulated from state tort liability to the extent that it has complied with FDA-approved specifications and federal statutory provisions and regulations governing the device. *Hughes*, 631 F.3d at 767-69; s*ee also Riegel*, 552 U.S. at 329 (affirming dismissal of claims interpreted by district court as asserting that device "violated state tort law *notwithstanding* compliance with the relevant federal requirements") (emphasis added). This protection ends, however, where the state-law claim is premised on the manufacturer's violation of the applicable federal requirements. *See Riegel*, 552 U.S. at 330; *Bass*, F.3d at 508-09, 514-18 (no preemption of state-law claims based on allegation that PMA-approved device was manufactured in violation of FDA requirements); *Hughes*, 631 F.3d at 769-71, 776 (no preemption of claim that manufacturer violated state-law duty to warn by failing to comply with FDA reporting requirements). In such case, the state-law duties "parallel," rather than add to, those requirements, and the claim fails to satisfy the second prong. *Id.*

C. Summary Judgment Evidence

AMS submits the affidavit of Amy Peterson, AMS Senior Director of Regulatory Affairs, attesting that the "AMS 700 Penile Prosthesis Product Family of Products" ("AMS 700") is a Class III prescription medical device designed and manufactured by AMS and approved by the FDA via the PDP process. (Dkt. No. 37-1 at ¶¶ 3, 5, 7). To receive PDP approval, AMS "submitted a summary of the AMS 700's safety and effectiveness, device design and manufacturing information, performance standards, technical data—including testing, a bibliography, labeling and warning information, clinical data supporting the safety and effectiveness of the AMS 700 and any additional information the FDA required." *Id.* at ¶ 9. Peterson attests that the FDA gave initial PDP approval of the AMS 700 on November 2, 1998, and references an attached letter declaring the PDP completed subject to FDA-imposed

conditions. *Id.* at ¶ 10, Exh. A. Peterson states that the FDA gave further approval of the AMS 700, including the AMS 700 "MS" identified in Plaintiff's pleading, on February 3, 2006. *Id.* at ¶ 11. The exhibit referenced to support this statement consists of a letter from the FDA acknowledging completion of AMS' PDP supplement, "which requested approval for design and packaging modifications to the pump (the AMS 700 MS Pump), cylinder, rear tip extender, and reservoir components, as well as associated labeling changes." *Id.* at ¶ 11, Exh. B. The letter states that "[b]ased upon the information submitted, the PDP supplement is approved," and that "you [AMS] may begin commercial distribution of the device as modified by your PDP supplement" in accordance with FDA-imposed conditions. *Id.* at Exh. B. Peterson's affidavit also states that Plaintiff's "Patient Information Form" received by AMS, and attached as an exhibit, demonstrates that "the inflatable device implanted into [Plaintiff] was the AMS 700 MS and was manufactured subsequent to PDP approval." *Id.* at 12, Exh. C.

D. Analysis

The Court concludes, over Plaintiff's various objections, that the affidavit and attached evidence are admissible in their present form. *See* (Dkt. No. 38). Further, Plaintiff fails to call into serious question whether the AMS device implanted into him has received PDP approval. That AMS delayed in submitting the February 3, 2006 letter is merely reflective of the fact that, subsequent to the Court's partial conversion of the Motion, Plaintiff objected to the absence of any reference to the "MS" series in the November 2, 1998 letter declaring PDP completion of the AMS 700. (Dkt. No. 36). Further, although Plaintiff alleges that his own Internet search "has not found any evidence of specific approval for the 'MS' model," the attached screen capture of Plaintiff's search results supports AMS' evidence that the AMS 700 received FDA approval on November 2, 1998, and also reflects that "[t]his medical device has supplements." (Dkt. No. 38-

1). Although the various identification and lot numbers on Plaintiff's "Patient Information Form" do not indicate the date that the device implanted into Plaintiff was manufactured, the Form does reference the "MS Pump." *See* (Dkt. No. 37-1 at Exh. C). The Court finds that no genuine dispute exists as to whether the AMS 700 (inclusive of the "MS Pump") had received a declaration of PDP completion, and therefore FDA approval, as of the undisputed date of Plaintiff's surgery. Therefore, the absence of an indicated date of manufacture on the Form is insufficient to require discovery on this matter. In sum, the Court concludes that AMS has satisfied the first prong of the MDA preemption test.

Plaintiff claims that even if AMS can show FDA approval of the device in question, it cannot meet the second prong of the preemption test because Plaintiff's claims "are not in addition to or different from any specific restriction from the FDA to the AMS 700 MS device." (Dkt. No. 38). For the reasons explained *supra*, the fact that this device has received a declaration of PDP completion means that the FDA considers it to have survived the requisite cost-benefit analysis, and to be reasonably safe and effective. It also means that the device must conform to FDA-approved specifications and applicable federal statutory provisions and regulations. Thus, to identify a "parallel" claim, as Plaintiff is attempting to do, he must articulate how AMS' alleged violation of the duties imposed by the particular claims he asserts equates to a violation of the governing federal requirements.

The Court first notes that Plaintiff need not assert a "parallel" breach of contract cause of action because the "state requirements" to which the MDA refers include state common-law duties, not contractual duties even if enforced through state law. Still, the claim as pleaded is conclusory and devoid of any factual support: Plaintiff alleges that the "actions and/or omissions" of both AMS and dismissed Defendant Dr. Ruiz constitute a breach of contract, but

offers no indication of what contract between Plaintiff and AMS was breached, or how. (Dkt. No. 1-2, Exh. A at ¶ 17). This claim therefore falls short of the Rule 12(b)(6) pleading standard to which AMS' Motion alternatively appeals, and must be dismissed.

Plaintiff's DTPA claims are also conclusory—he makes reference to the DTPA's protection against "false, misleading and deceptive acts, practices and/or omissions," and to the section of the statute that defines "unconscionable action or course of action," without indication of the specific statutory or factual bases for this cause of action against AMS. *See id.* at ¶¶ 15-16; TEX. BUS. & COM. CODE § 17.45(5). When considered against the "Facts" section of the pleading, the Court can make an educated guess as to those bases. Plaintiff describes various alleged deficiencies in the device or in the manner in which it was implanted, the resulting pain and disfigurement experienced by Plaintiff "in the area of the procedure" and when operating the device, and the degree to which the device has failed to produce an erection as promised in AMS' "brochures and literature" on which Plaintiff relied. *See* (Dkt. No. 1-2, Exh. A at ¶ 8). Arguably, therefore, Plaintiff is making a DTPA claim that misrepresentations in AMS' "brochures and literature" constitute a "false, misleading, or deceptive act or practice" enumerated in § 17.46(b), and an "unconscionable action or course of action" for which AMS may be held liable. *See* TEX. BUS. & COM. CODE §§ 17.50(a); 17.46(b), 17.45(5). Plaintiff's responsive briefing now argues that all of his claims parallel FDA requirements which prohibit "deceiving the public when marketing medical devices," but he fails to articulate how AMS' marketing, through its brochures and literature, deviated from the FDA-approved form. (Dkt. No. 38). Therefore, this argument fails to identify a parallel claim. *See Bass*, 669 F.3d at 515, 518 (DTPA claim premised on "marketing defect" preempted where plaintiff failed to plead specific facts as to how marketing violated FDA regulations). With respect to his final cause of

action—that AMS may be held strictly liable for its defective or unreasonably dangerous device—Plaintiff also fails to plead or otherwise explain how he has premised this claim on the violation of an applicable federal requirement. *See* (Dkt. No. 1-2, Exh. A at ¶¶ 9-11). In *Bass*, the plaintiff sufficiently pleaded a parallel strict liability claim under Texas law by alleging that the FDA warned the manufacturer of excess contaminant in its device, the device implanted into the plaintiff was recalled because of contamination issues, and the plaintiff's device caused the type of injury consistent with excess contamination. *Bass*, 669 F.3d at 510-11, 514-15. Plaintiff essentially asks the Court to assume the violation of a federal requirement because he has alleged that the AMS device implanted into him caused him pain and/or did not work as promised, but governing case law does not recognize a parallel claim premised on such an assumption.

IV. Conclusion

For all of these reasons, the Court finds that Plaintiff's breach of contract cause of action fails to state a claim upon which relief can be granted and hereby **ORDERS** that AMS' Rule 12(b)(6) Motion to Dismiss is **GRANTED** with respect to this claim.

Further, the Court concludes that no genuine issue of material fact exists on whether the AMS medical device implanted into Plaintiff received FDA approval through PDP completion, and that Plaintiff's DTPA and strict liability causes of action are preempted under the MDA. Accordingly, the Court hereby **ORDERS** that AMS' Partially Converted Rule 56 Motion for Summary Judgment is **GRANTED** with respect to Plaintiff's remaining claims.

The Court will enter a separate final judgment.

SO ORDERED this 4th day of February, 2014, at McAllen, Texas.

Randy Crane
United States District Judge